THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 35

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte VINOD R. HEGDE, ANN C. HORAN,
MAHESH G. PATEL and INGRID-AGNETA GUNNARSSON

Appeal No. 94-1046
Application 07/747,456[1]

ON BRIEF

Before CAROFF, WILLIAM F. SMITH, and GRON, Administrative Patent Judges

GRON, Administrative Patent Judge.

DECISION ON APPEAL UNDER 35 U.S.C. § 134

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[1] Application for patent filed August 12, 1991. According to applicants, this application is a continuation of Application 07/590,315, filed September 28, 1990, now abandoned; which is a continuation of Application 07/227,968, filed August 3, 1988, now abandoned.

This is an appeal from an examiner's rejections of Claims 1-9, all claims pending in this application.

1. The claimed subject matter

Claim 1 is representative of the claimed macrolactam monosaccharide antimicrobial compound and is reproduced in the attached Appendix. All claims stand or fall together (Brief on Appeal, p. 4).

The claims are directed to a macrolactam monosaccharide antimicrobial compound in substantially pure form, its pharmaceutically acceptable salts, pharmaceutical compositions comprising the pure compound or its salts, and methods for their administration to hosts having a susceptible microbial infection. "The compound is isolated from an antimicrobial complex 517 which is produced in fermentation under controlled conditions using a biologically pure culture of the microorganism, Actinomadura vulgaris subsp. vulgaris SCC 1776, ATCC 53748" (Specification (Spec.), p. 1, introductory paragraph). The microorganism was isolated from soil collected in Borneo (Spec., p. 3, last paragraph).

2. The rejections

A. Claims 1-9 stand rejected under 35 U.S.C. § 112, first paragraph, purportedly because the specification, as originally filed, did not describe the compound of formula 1 of Claim 1.

B. Claims 1-9 stand rejected under 35 U.S.C. § 103 as being unpatentable in view of antibiotic AB-85 disclosed in Japanese Patent Publication 59-18035, published April 25, 1984.

C. Claims 1-9 stand provisionally rejected for obviousness-type double patenting of Claims 1-12 of commonly assigned copending Application 07/746,050.

D. Claims 1-9 stand provisionally rejected for obviousness-type double patenting of Claims 1-9 and 11 of commonly assigned Application 07/746,059.

3. Discussion

A. Description requirement of Section 112

We reverse the rejection of the claimed subject matter for noncompliance with the description requirement of the first paragraph of 35 U.S.C. § 112. The examiner's doubts that the specification, as originally filed, describes the compound of formula 1 of Claim 1, have not been adequately explained.

Compliance with the description requirement of 35 U.S.C. § 112, first paragraph, is a question of fact. Vas-Cath Inc. V. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). To satisfy the description requirement, the specification as originally filed must convey to persons skilled in the art that applicants invented the subject matter claimed. In re Wilder, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984);

In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983). However, compliance with the description requirement does not require that the invention be described ipsis verbis in the specification. In re Lukach, 442 F.2d 967, 969, 169 USPQ 795, 796 (CCPA 1971). The first paragraph of Section 112 only requires that the description in the specification would have clearly allowed persons skilled in the art to recognize that applicants invented the subject matter claimed. In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

The examiner has the initial burden to explain why persons skilled in the art would not have recognized a description of the compound defined by formula 1 of Claim 1 in the specification. In re Gosteli, supra; In re Wertheim, 541 F.2d 257, 263, 265, 191 USPQ 90, 97, 98 (CCPA 1976). Thus, faced with the qualitative data in the specification and identical limitations in Claim 1, including the NMR and IR spectroscopy and optical rotation information presented in Table II at page 14 of the specification, the argument by the examiner that formula 1 of Claim 1 is not drawn in precisely the same manner as formula 1 on page 2 of the specification does not itself satisfy the examiner's burden to explain why applicants' specification would not have described the compound presently claimed to persons skilled in the art. This is especially true when, as here,

Mohindar S. Puar, a person with much experience interpreting NMR and IR data, declares that the compound spectroscopically described in Table II on page 14 of the specification is the same compound represented by the formula now appearing in Claim 1 based on his review of the NMR, IR, and optical rotation data in the specification (pages 2-3, bridging paragraph, of the Declaration of Mohindar S. Puar, Paper No. 26, filed March 26, 1992). In essence, Puar declares that the data in the specification necessarily describes the inventive compound appellants now claimed. It is not clear why, but the examiner is not satisfied.

The examiner does not contradict the Puar Declaration. Rather, the examiner appears to be arguing that appellants have not proven that formula 1 of Claim 1 is the "necessary and only reasonable" formula to be given to the compound spectroscopically described on page 14 of the specification. What is the problem? The examiner answers that Puar's declaration is not persuasive "because appellants have not presented any objective evidence showing that the said physicochemical data is not consistent with the structural formula presented in the specification, as originally filed" (Examiner's Answer, paragraph bridging pages 5-6). We are confused by these remarks.

The examiner does not explain why the data on page 14 of the specification does not represent the structural formula depicted in Claim 1 as Puar declares and does not constitute objective evidence that appellants invented the subject matter of Claim 1 at the time their application was originally filed. We can speculate why the examiner maintained the rejection, but we decline to do so.

Decisions by the Board are based on sound reasoning supported by evidence. Absent some reasonable explanation by the examiner as to why the data on page 14, especially data which the art of qualitative analysis recognizes as being capable of distinguishing isomers (compare the data reported in Tables II and III of the specification, pp. 14 and 16 respectively, and Table IV, p. 17), does not correspond to formula 1 of Claim 1, we reverse the examiner's rejection.

B. Obviousness under Section 103

The examiner has the initial burden of making out a case for obviousness under 35 U.S.C. § 103. The examiner's case for obviousness is supported by the following arguments (Examiner's Answer, p. 4):

> The Japanese patent discloses a closely analogous antibiotic having the molecular formula of $C_{25}H_{28}N_2O_5$. The only difference between the claimed compound and the reference's compound is a position of a hydroxy group at the 4'-position. Since the claimed compound is a position isomer of the reference's compound and

> since a person having ordinary skill in the art at the time the instant invention was made would have expected the claimed compound to have biological activity similar to that of the reference's compound, the claimed compound, composition containing the same and methods of treatment would have been prima facie obvious to a person having ordinary skill in the art at the time the instant invention was made.

The two-part criteria for holding that a claimed compound would have been obvious under Section 103 over the disclosure of a structurally similar compound in the prior art is set out in In re Payne, 606 F.2d 303, 313-15, 203 USPQ 245, 254-255 (CCPA 1979) and is particularly applicable to this case. First, would the undisclosed structure of the AB-85 antibiotic described by Japan be understood by persons having ordinary skill in the art to be so similar to formula 1 of appellants' Claim 1 that they reasonably would have been led to make and use the compound of formula 1 of Claim 1 for its antibiotic function with reasonable expectation of success. Id. at 313, 203 USPQ at 254. Second, would the prior art have enabled persons skilled in the art to make and use the claimed compounds, i.e., would it have placed the claimed compound in the possession of the public. In re Payne, 606 F.2d at 314-15, 203 USPQ at 255. We need not dwell on the first criteria, because the examiner has not supported his allegation that the claimed antibiotic compound would have been obvious with evidence sufficient to justify a conclusion that the prior art would have enabled one skilled in the art to make and

use appellants' antibiotic compound without appellants' disclosure.

In his declaration filed March 26, 1992 (Declaration of Min Chu (Chu), Paper No. 26), Chu declares (Chu, pp. 2-3):

> THAT, the structural formula of the antibiotic AB-85 . . . of the Japanese patent . . . [has] the formula 2 of this Application . . .[; and]
>
> THAT, based on information and belief and my expertise in synthetic organic chemistry, I am aware of no synthetic chemical method in existence as of August 3, 1988 of synthesizing the compound of this invention . . . except by the fermentation of Actinomadura vulgaris subsp vulgaris of this invention . . . .

In short, Min Chu declares that he knows of no method of preparing antibiotics including the 3-amino-3,6-dideoxytalo-pyranose radical which is attached as the talopyranoside to C-6 of the macrolactam aglycone of this invention from antibiotics including the 3-amino-3,6-dideoxymannopyranose radical which is attached as the mannopyranoside to C-6 of the macrolactam aglycone AB-85 (Chu, page 3).

Faced with Chu's declaration, the examiner responded as follows (Examiner's Answer, pp. 6-7):

> Even though the Japanese patent does not disclose the structural formula of antibiotic AB-85, it would have been within the ordinary skill in the art at the time the instant invention was made to determine the same using conventional techniques for structural analysis. As shown on page 3 of the Declaration by Dr. Puar, the only difference between the claimed compound and the reference's compound is the position of hydroxy group at the 4'-position on a sugar moiety. . . .

> With respect to the synthesizing of the claimed compound, note that the instant claims are not directed to the process claims but to product claims. Further, it would have been obvious to a person having ordinary skill in the art at the time the instant invention was made to prepare the claimed compound by removing the sugar moiety of the reference's compound by acid hydrolysis and by reacting the resulting aglycone with the desired sugar moiety.

While Chu's declaration of unobviousness is itself supported by no more evidence than is the examiner's allegation of obviousness, it is the examiner who has the initial burden to sustain his case. In our view, the examiner's case of obviousness under 35 U.S.C. § 103 in view of the teaching of Japan 59-18035 is purely speculative. Accordingly, we reverse the rejection.

C. Obviousness-type double patenting

The provisional obviousness-type double patenting rejection of Claims 1-9 in view of the subject matter of Claims 1-9 and 11 of Application 07/746,059 is hereby reversed. The rejection is moot because the application appears to have been abandoned.

We reverse the examiner's provisional obviousness-type double patent rejection of Claims 1-9 in view of the subject matter of Claims 1-12 of commonly assigned, copending Application 07/746,050. The examiner finds (Examiner's Answer, p. 3, first full paragraph):

> . . . [T]he conflicting claims are not identical . . . because the difference between the claimed compound and

> the compound of the copending application is at the 5, 9, or 13 positions. The compound of the copending application has a methyl group at the 5, 9, or 13 position instead of ethyl. Since ethyl is a next higher homologue of methyl, the claimed compound is an obvious variant of the compound claimed in the copending application.

The examiner's finding is clearly erroneous. The difference between the claimed compound and the compound of the copending application lies not only at the 5, 9, or 13 position of macrolactam aglycone ring of the claimed antibiotics but also in the difference between the 3-amino-3,6-dideoxytalopyranose isomer which is attached to C-6 of the macrolactam aglycone ring of the compound claimed in this application and the 3-amino-3,6-dideoxymannopyranose isomer which is attached to C-6 of the macrolactam aglycone ring of the compound claimed in the copending application. As we indicated with respect to the examiner's rejection of Claims 1-9 under 35 U.S.C. § 103 in view of the teaching of Japan 59-18035, the examiner has not established that a disclosure of one isomer would have enabled persons skilled in the art to make and use the other.

4. Conclusions

We reverse all the examiner's rejections.

REVERSED

Marc L. Caroff Administrative Patent Judge	)	
William F. Smith Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
Teddy S. Gron Administrative Patent Judge	)	

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